



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Lubman, *et al.*
Serial No.: 09/778,496 Group No.: 1631
Filed: 02/07/01 Examiner: Mahatan
Entitled: **MAPPING OF DIFFERENTIAL DISPLAY OF PROTEINS**

**DECLARATION OF DAVID M. LUBMAN, Ph.D.
UNDER 37 CFR § 1.132**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Dated: 8-18-04

By: David M. Lubman

Examiner Mahatan:

I, David M. Lubman, hereby declare and state, under penalty of perjury, that:

1. I am one of the inventors of the above-named patent application (hereinafter "present application"). I have worked in the field of protein separation and display for many years and have numerous publications in this field.

2. I am a co-author of the publication entitled "Rapid screening of protein profiles of human breast cancer cell lines using non-porous reversed-phase high performance liquid chromatography separation with matrix-assisted laser desorption/ionization time-of-flight mass spectral analysis," Chong et al., *Rapid. Commun. Mass. Spectrom.* 13:1808 [1999] (hereinafter Chong), which has been cited by the Examiner as prior art in the present case.

3. I have read and reviewed the following prior art publications cited by the Examiner in the above-named case: Richmond et al., "High-throughput flow injection analysis-mass spectrometry with network delivery of colour rendered results: the characterization of liquid chromatography fractions," J. Chromatography 1999. 835:29 (hereinafter Richmond) and Pandey and Mann, "Proteomics to study genes and genomes," Nature 2000. 405:837 (hereinafter Pandey).

4. The Chong reference does not describe a protein profile map where the protein profile map includes a display of each protein in a sample as a separate band corresponding to the mass of the protein where the intensity of the band corresponds to the abundance of the protein in the sample.

5. The Chong reference does not describe the side by side display of two protein profile maps.

6. The Chong reference does not describe a switchable, multichannel valve for use in delivering sample from one apparatus to another.

7. The Chong reference does not describe the use of electrospray ionization-orthogonal acceleration-time-of-flight mass spectrometry.

8. The Chong reference does not describe or suggest that there are any deficiencies in the methods of displaying mass spectrum that are used in the reference.

9. The Chong reference does not describe a need for alternative methods for the display of mass spectrum. The display methods described in Chong are perfectly suitable for the scientific questions addressed in the Chong reference. Therefore, a scientist reading the Chong reference would have no particular motivation to alter the display methods or use different display methods.

10. The Chong references teaches standard methods of mass spectrum display that

would have been used by someone working in the field of protein separation and analysis at the time the reference was published.

11. The Richmond reference does not describe a protein profile map or any work related to protein analysis.

12. The Richmond reference does not describe a protein profile map where the protein profile map includes a display of each protein in a sample as a separate band corresponding to the mass of the protein where the intensity of the band corresponds to the abundance of the protein in the sample.

13. The Richmond reference does not describe the side by side display of proteins.

14. The Richmond reference does not describe a switchable, multichannel valve for use in delivering sample from one apparatus to another.

15. The Richmond reference does not describe the use of electrospray ionization-orthogonal acceleration-time-of-flight mass spectrometry.

16. The Richmond reference is in the field of chemical analysis.

17. The Richmond reference would not have been consulted by someone working in the field of protein separation and analysis to solve problems in protein display, as this reference is in a different field and has no bearing on protein analysis.

18. There is no scientific basis in any of the references cited by the Examiner that would lead someone to apply the display methods of Richmond to the methods of Chong.

19. The Pandey reference reviews current methods in proteomics at the time the reference was published, including mass spectrum display methods.

20. The Pandey reference does not describe a protein profile map.
21. The Pandey reference does not describe a map that includes the display of each protein in a sample as a separate band corresponding to the mass of the protein where the intensity of the band corresponds to the abundance of the protein in the sample.
22. The Pandey reference does not describe the side by side display of two protein profile maps.
23. The Pandey reference does not describe a switchable, multichannel valve for use in delivering sample from one apparatus to another.
24. The Pandey references teaches standard methods of mass spectrum display that would have been used by someone working in the field of protein separation and analysis at the time the reference was published.
25. The Pandey reference does not describe deficiencies in the methods of displaying mass spectrum that were used at the time the reference was published.
26. The Pandey reference does not describe a need for alternative methods for the display of mass spectrum. Therefore, a scientist reading the Pandey reference would have no particular motivation to alter the display method or use different display methods.
27. There is no scientific basis in any of the references cited by the Examiner that would lead someone to apply the display methods of Richmond to the methods of Pandey.
28. I declare that all statements made herein are of my own knowledge and are true, and further that those statements are made with the knowledge that willful false statements and the like so mare are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code, and that such willful, false statements may jeopardize the validity of the patent application or any patent issuing therefrom.

David M. Lubman, Ph.D.

David M. Lubman, Ph.D.

8/10/04

Date